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14. ABSTRACT The primary goal of this analysis was to identify scientific and policy goals, needs, and challenges of current United States government (USG) international disease surveillance. A secondary goal was to foster communication and collaboration among the Defense Threat Reduction Agency (DTRA), other USG agencies, non governmental organizations (NGOs), academia, and other parties engaged in international disease surveillance activities. The report's findings include:				
<ol style="list-style-type: none"> 1. The existence of multiple major U.S. goals for international disease surveillance requires distinct USG approaches. 2. Targeted USG investment could strengthen international disease surveillance. 3. Potential opportunities exist for improving USG implementation of international disease surveillance programs. 				
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Center for Biosecurity of UPMC



INTERNATIONAL DISEASE SURVEILLANCE: UNITED STATES GOVERNMENT GOALS AND PATHS FORWARD

June 2010

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Executive Summary

PURPOSE

To assist the Defense Threat Reduction Agency's Chemical and Biological Technologies Directorate (DTRA/RD-CB) in evaluating its current and future role,* the primary goal of this analysis was to identify scientific and policy goals, needs, and challenges of current United States government (USG) international disease surveillance efforts. A secondary goal was to foster ongoing communication and collaboration among DTRA, other USG agencies, NGOs, academia, and other parties engaged in international disease surveillance activities.

INTRODUCTION

Historically, the USG has offered aid and assistance to foreign governments for the betterment of global health. Recently, interest in increasing the USG's role in international disease surveillance has grown. The increased incidence of emerging infectious diseases, such as SARS and the 2009 H1N1 influenza pandemic, and post-2001 concerns about the potential use of biological weapons have demonstrated a need for greater U.S. involvement in efforts to strengthen international disease surveillance.

The Obama Administration has articulated the importance of international disease surveillance as a component of U.S. national security. In 2009, the U.S. National Security Council called for enhanced disease surveillance, detection, diagnosis, and reporting as a fundamental pillar of the U.S. biological threat prevention strategy.¹ Over the last decade, several important nongovernmental reviews by such groups as the National Academy of Sciences and the National Biosurveillance Advisory Subcommittee (NBAS) have called upon the USG to enhance national security by strengthening its engagement with international partners to build capacity for detecting, reporting, and responding to disease outbreaks.^{2,3,4,5}

The U.S. has a legal obligation to work with international partners to improve global capacity to detect and respond to disease threats. In 2005, the International Health Regulations (IHRs)—which provide a legal framework for improving global public health—were revised to require states parties to build and maintain the capacity to detect and respond to public health events of international concern (PHEICs) and to report these events to the World Health Organization (WHO) within 24 hours.⁶ To help countries with few resources comply with the revised IHRs, the regulations also require the U.S. and other signatories to provide assistance.

* This analysis was conducted by the Center for Biosecurity of UPMC (the Center) under contract to the Defense Threat Reduction Agency's Chemical and Biological Technologies Directorate (DTRA/RD-CB) through The Tauri Group.

ANALYSIS AND WORKSHOP

To inform this analysis, Center staff conducted an extensive review of the scientific literature pertaining to international disease surveillance. In addition, the Center held preliminary conversations with close to 30 subject matter experts from academia, government, and nongovernmental organizations (NGOs) in the field of disease surveillance (see Appendix A, page 23). These detailed conversations addressed the current status of international disease surveillance and explored the potential for increased involvement by DTRA. Based on this analysis, the Center prepared a Preliminary Analysis Report (delivered on March 24, 2010) that provided the structure for a workshop meeting held at the Center on March 31, 2010.

The workshop was attended by more than 30 people, including experts from the group noted above, as well as staff and leaders from DTRA and the Center. The workshop served as a forum for in-depth discussion and focused on the Center's synthesis of the goals, needs, challenges, and funding priorities of USG international disease surveillance efforts. Consensus was not sought among workshop participants, but the points raised and primary themes of the discussion were captured for this final report.

FINDING 1: The existence of multiple major U.S. goals for international disease surveillance requires distinct USG approaches.

The Center's analysis found that 5 major goals (below) drive USG international disease surveillance efforts. It is important to understand and account for these related but distinct goals when considering programmatic and investment strategies to improve international disease surveillance.

GOALS:

1. Bolster overall public health capacity of other countries to help them assess the impact of endemic diseases and differentiate outbreaks from endemic disease.
2. Obtain early warning about outbreaks of human disease.
3. Predict future human disease threats by monitoring zoonotic disease outbreaks and diseases that circulate within animal populations.
4. Obtain information to help maintain situational awareness during an epidemic in order to facilitate response.
5. Fulfill U.S. obligations under the IHRs to assist other countries in developing the capacity to detect, report, and respond to PHEICs.

FINDING 2: Targeted USG investment could strengthen international disease surveillance.

The Center identified 5 critical international disease surveillance needs that, if met, would move the U.S. toward achieving the 5 goals cited above (Finding 1). To that end, the USG should consider investing in these 5 areas:

1. Increasing numbers of trained in-country personnel.
2. Developing flexible tools for information acquisition and analysis that promote communication between public health and healthcare professionals.
3. Improving surveillance for zoonoses by incorporating the collection and analysis of animal health data into human health surveillance programs.
4. Improving laboratory and diagnostic capacity to detect and characterize important pathogens.
5. Developing surveillance systems that meet routine surveillance priorities of host nations and provide for surveillance of emerging infectious diseases and other health security threats.

FINDING 3: Potential opportunities exist for improving USG implementation of international disease surveillance programs.

The following represent opportunities for USG agencies to improve implementation of U.S. international disease surveillance programs:

1. Improve coordination among USG agencies involved in international surveillance. To date, the lack of coordination among USG agencies has made it difficult to gauge the overall impact of efforts or to prevent the duplication of effort. In some cases, lack of coordination may result in program initiatives that work at cross-purposes.
2. Improve USG coordination with foreign governments and NGOs involved in disease surveillance. Increased interest in disease surveillance among foreign governments and NGO donors has produced separate surveillance systems and offers of assistance that may be duplicative and may overwhelm data providers. Increased coordination at the regional or international level is important to increase the reach and success of disease surveillance efforts.
3. Address international perceptions of military/intelligence/commercial use of disease surveillance data. In engaging foreign governments for the purposes of international disease surveillance, U.S. agencies should be aware that actual or perceived uses of data for U.S. intelligence, military, or commercial applications may be a significant barrier to cooperation.

Center for Biosecurity Recommendations

The following recommendations represent the Center's independent assessment, based on our literature review and analysis, interviews with experts, and advisory input from the expert workshop on international disease surveillance.

1. **Improve strategy and coordination:** The USG should develop a comprehensive strategy to guide future programs and investments in international disease surveillance; doing so will enhance U.S. opportunities to meet its major goals for international disease surveillance. Involvement of multiple USG agencies in international disease surveillance and pursuit of multiple goals will require enhanced coordination across the USG. This will ensure that distinct goals are being pursued effectively and that agencies are not unintentionally working at cross-purposes and/or duplicating efforts. Therefore, the USG should continue efforts to develop improved processes for interagency coordination, and those efforts should include strategies for coordinating with foreign governments and NGOs that may also be involved in international disease surveillance efforts.
2. **Address in-country surveillance priorities:** USG international disease surveillance programs should include support for local surveillance and response priorities. Improving local capacity to address routine infectious disease needs of host countries will improve or lead to the technical ability to detect and respond to emerging infectious diseases and other health security threats. It will also serve to increase local support for USG and other nongovernmental disease surveillance programs.
3. **Tie surveillance programs to public health actions:** To the greatest extent possible, the development of disease surveillance programs should be tied to public health action. Surveillance data that is collected should be evaluated continually for its role in informing public health decisions and interventions. After-action reports from exercises and real public health emergencies should be used to evaluate the ability of surveillance systems to provide actionable information to guide public health response to health threats.
4. **Expand global lab capacity for human and animal diseases:** USG disease surveillance programs should continue to support efforts to expand global laboratory and diagnostic capacity for both human and animal diseases in order to improve detection and management of infectious disease threats. In addition to supporting development of specific plans for how to appropriately increase laboratory capacity worldwide, the USG would be wise to invest in efforts to develop rapid, point-of-care diagnostic tests that can quickly identify people who are ill and help to isolate contagious people.
5. **Maintain transparency and stewardship of surveillance data:** In engaging foreign governments for the purposes of international disease surveillance, USG agencies should work to alleviate concerns that foreign public health surveillance data will be used for U.S. intelligence, military, or commercial applications. Most important to this effort are continual maintenance of transparency, good stewardship of host country data, and the continued support of surveillance programs that produce tangible benefits for host nations by addressing local disease priorities and providing data that can be used to inform public health action.

6. Develop a cadre of skilled in-country personnel to staff and manage disease surveillance

systems: The success of any disease surveillance program will require skilled personnel who have local knowledge and are well-trained in epidemiology and laboratory methods (including biosafety and quality control). However, in much of the world there are critical shortages of such workers.

To address this issue, the USG should continue to support efforts to train in-country personnel to staff and manage surveillance programs. To that end, the USG should consider expanding existing training programs, such as the CDC's Field Epidemiology Training Program (FETP) and Field Epidemiology Laboratory Training Program (FELTP). The FETP and FELTP efforts are generally well regarded, and new efforts by FELTP to train veterinary health professionals to participate in surveillance for zoonoses is a promising development.

7. User requirements should drive development of flexible surveillance tools that, at a minimum,

support connections between public health and healthcare sectors: Lessons from previous outbreaks have demonstrated that, in many areas, connections between public health and healthcare sectors are not sufficient to support effective detection of and response to outbreaks.

The USG should support development of flexible tools to support improved communication between these 2 sectors. However, rather than approaching partner countries with a particular tool or technology in hand, the USG should first assess the specific needs of users in host countries. Such an assessment should be completed prior to systemic deployment of a surveillance technology or tool and should involve all stakeholders, including data providers, data users, and the host country's ministry of health.



International Disease Surveillance: United States Government Goals and Paths Forward

INTRODUCTION

The Center for Biosecurity of UPMC (the Center), under contract to the Defense Threat Reduction Agency (DTRA) through The Tauri Group, undertook a project entitled “International Disease Surveillance: United States Government Goals and Paths Forward.” This project focused on overarching issues related to USG interests in improving international surveillance for infectious diseases. The specific goals of the project were to provide DTRA leadership with expert judgments regarding the following:

1. Primary goals of international disease surveillance and the extent to which they are being met.
2. Priority areas for USG investment.
3. Ways to address major challenges to successful implementation of USG international disease surveillance efforts.

The project also sought to foster ongoing communication and collaboration among DTRA, other USG agencies, NGOs, academia, and other parties engaged in international disease surveillance. Although several USG agencies were consulted for this project, this review did not analyze specific agency roles or responsibilities.

This project was undertaken because enhanced U.S. involvement in international disease surveillance has become an important national security policy issue for the USG. The Obama Administration has articulated the importance of international disease surveillance as a component of U.S. national security. In 2009, the U.S. National Security Council called for enhanced disease surveillance, detection, diagnosis, and reporting as a fundamental pillar of the U.S. biological threat prevention strategy.⁷

Over the last decade, several outside reviews have called upon the USG to enhance national security by strengthening its engagement with international partners to build capacity to detect, report, and respond to disease outbreaks. Multiple reports issued by the National Academy of Sciences have called for expansion of DTRA’s Cooperative Threat Reduction (CTR) program to include: (1) regions beyond the former Soviet Union; and (2) greater emphasis on helping partner countries improve their capacities for disease surveillance. In addition, in April 2009, the National Disease Surveillance Advisory Subcommittee—the federal advisory group created by the White House in 2006 to evaluate national investments in disease surveillance, concluded in

its first public report that it was in the interest of U.S. national security for “the U.S. National Bio-surveillance Enterprise [to] include global health threats in its purview and scope.”⁴

In addition to pursuing international disease surveillance for its own interests, the U.S. has a legal obligation to work with international partners to improve global capacity to detect and respond to disease threats. In 2005, the International Health Regulations (IHRs)—a legal framework for improving global public health—were revised to require that states parties build and maintain the capacity to both detect and respond to public health events of international concern (PHEICs) and to report these events to the World Health Organization within 24 hours.⁶ The United States and other signatories of the revised IHRs are required to provide assistance to help countries with limited resources achieve compliance with IHRs.

METHODS

To complete this analysis, the Center conducted a series of discussions with leaders in the field of disease surveillance from academia, NGOs, and the USG. Discussion topics were derived from several sources: extensive review of USG international disease surveillance programs; discussions with thought leaders in this field; and review of the published literature, key policy analyses, and reports from the National Academy of Sciences. In each preliminary conversation with an expert, we addressed high-level goals of USG involvement in international disease surveillance, specific information needs of federal agencies, the extent to which current approaches are meeting USG needs and goals, and potential challenges to enhanced USG engagement in international disease surveillance.

The project culminated in a workshop on March 31, 2010, with more than 30 participants from academia, NGOs, and the USG (see Appendix A, page 23). Senior staff and leadership from DTRA and the Center for Biosecurity also attended. Prior to the workshop, the Center completed a Preliminary Analysis Report to provide a synthesis of the literature and information obtained during our conversations with experts. Those findings were used to facilitate the workshop discussion.

This final report presents a synthesis of the Center’s scientific and policy review, a synopsis of the workshop discussions, and brief summary conclusions from the Center for Biosecurity.

Both the workshop discussion and our pre-meeting phone conversations with experts were held on a not-for-attribution basis. Quotes from project participants appear in italics throughout this report. Expert input at the workshop and in the preceding interviews was considered advisory to the analysis. The Center did not attempt to achieve consensus in any of its discussions with experts. Accordingly, the findings and recommendations in this report represent Center for Biosecurity analysis, though the great majority of them would be supported by most of the experts who advised this project.

Overview of Major USG Programs for International Disease Surveillance

There are now in place many USG programs engaged with international partners to improve surveillance for important diseases. Our review found evidence of disease surveillance programs or related activities in a large number of agencies: U.S. Department of Health and Human Services (HHS), U.S. Department of Defense (DoD), Department of State (State), U.S. Agency for International Development (USAID), U.S. Department of Homeland Security (DHS), U.S. intelligence agencies, U.S. Department of Agriculture (USDA), U.S. Department of Commerce (Commerce), U.S. Department of Transportation (DOT), U.S. Department of Energy (DOE), U.S. Department of the Interior (DOI), U.S. Environmental Protection Agency (EPA), National Aeronautics and Space Administration (NASA), and U.S. Postal Service (USPS). However, the majority of activities related to improving international disease surveillance and public health capacity to respond to infectious disease threats exists within a few agencies: the Centers for Disease Control and Prevention (CDC), the Department of Defense (DoD), the U.S. Department of State, and the U.S. Agency for International Development (USAID). Although not all of the programs identified below are focused specifically on international disease surveillance, all have been identified by external review as programs that should have an increased role in improving international disease surveillance. The Center determined that the USG spends around \$300 million/year on international disease surveillance activities within these 4 departments and agencies (Table 1).

Table 1: Annual Funding for Major USG Programs for International Disease Surveillance or Related Activities

AGENCY/PROGRAM		FY2009 (ACTUAL)	FY2010 (EST)	FY2011 (BUDGET)	TOTAL
HHS (CDC)	Global Disease Detection ¹	\$33.7 mil	\$37.7 mil	\$37.8 mil	\$109.2 mil
	Early Warning Infectious Disease Surveillance system (EWIDS) ²	\$5.0 mil	\$5.0 mil	\$5.0 mil	\$15.0 mil
	HHS Total	\$38.7 mil	\$42.7 mil	\$42.8 mil	\$124.2 mil
DoD	Biosecurity, Biosafety, Threat Agent Detection and Response ³	\$171.7 mil	\$133.3 mil	\$184.7 mil	\$489.7 mil
	Global Emerging Infections Surveillance and Response System (GEIS) ⁴	\$63.0 mil	\$68.3 mil	\$55.0 mil	\$186.3 mil
	DoD Total	\$234.7 mil	\$201.6 mil	\$239.7 mil	\$676.0 mil
State/ USAID	Biosecurity Engagement Program (BEP) ⁵	\$27.0 mil	\$37.0 mil	\$37.0 mil	\$101.0 mil
	USAID—infectious disease surveillance ⁶	\$25.0 mil	\$25.0 mil	\$25.0 mil	\$75.0 mil
	State/USAID Total	\$52.0 mil	\$62.0 mil	\$62.0 mil	\$176.0 mil
	Total USG Funding for International Disease Surveillance FY 2009 – FY 2011	\$325.4 mil. (actual)	\$306.3 mil. (est.)	\$344.5 mil. (budget)	\$976.2 mil.

1 U.S. Centers for Disease Control and Prevention. *FY2011 Justification of Estimates for Appropriation Committees*. 2010. Page 244. http://www.cdc.gov/fmo/topic/Budget%20Information/appropriations_budget_form_pdf/FY2011_CDC_CJ_Final.pdf. Accessed June 17, 2010.

2 Early Warning Infectious Disease Surveillance (EWIDS): Program Activities on the Northern and Southern Border States. GlobalSecurity. <http://www.globalsecurity.org/security/systems/ewids.htm>. Accessed June 17, 2010.

3 Franco C, Sell TK. Federal Biodefense Funding, FY2010-FY2011. *Biosecurity and Bioterrorism*, 2010;8(2).

4 U.S. Department of Defense, Armed Forces Health Surveillance Center. Personal Communication. Stephen Gubenja, Deputy Chief of Staff for Resource Management. June 18, 2010.

5 Franco C, Sell TK. Federal Biodefense Funding, FY2010-FY2011. *Biosecurity and Bioterrorism*, 2010;8(2).

6 United States Agency for International Development. *Disease Surveillance: Funding*. Updated June 2, 2009.

U.S. Centers for Disease Control and Prevention (CDC): The focal point of the CDC's international bio efforts is the Global Disease Detection (GDD) program, which was established in 2004 to rapidly identify and respond to outbreaks of novel infectious diseases.⁸ The GDD program currently comprises 6 regional centers located in Guatemala, Egypt, Kenya, Thailand, China, and Kazakhstan and an Atlanta-based Outbreak Information Center; an additional center is being established in India.⁹ The GDD regional centers build local and regional public health capacity by supporting detection of and response to emerging infectious diseases, health communication and information technology transfer, training in both field epidemiology and laboratory methods, and investigation and control of zoonotic diseases. The centers abroad utilize a mixture of surveillance technologies, including both syndromic and population-based approaches. The Atlanta-based Outbreak Information Center monitors surveillance data from a variety of sources (including local media reports and existing USG surveillance systems) to detect novel infectious disease events.

U.S. Agency for International Development (USAID): USAID's infectious disease surveillance strategy aims to build local capacity to collect, analyze, and make more effective use of infectious disease surveillance information. USAID supports regional and global organizations and also provides direct assistance to countries. The agency focuses support in 5 areas: improving diagnostic capability, incorporating behavioral science into the design of surveillance systems, developing country-based field epidemiology skills, developing appropriate analytical tools for local use, and improving the ability to act on surveillance information and respond effectively.¹⁰

U.S. Department of State (State): The State Department's Biosecurity Engagement Program (BEP) aims to develop cooperative international programs that promote the secure, safe, and responsible use of biological materials that may be intentionally misused or accidentally released. The program has 5 focus areas, one of which is surveillance and diagnostics, which has as its focus the provision of training in infectious disease surveillance and molecular diagnostics to support infectious disease detection and response. The program also builds laboratory capacity by training scientists, policymakers, and laboratory managers on surveillance, diagnostics, biosafety, and pathogen security.¹¹

Department of Defense (DoD): The Cooperative Threat Reduction (CTR) program, run by the Department of Defense's Defense Threat Reduction Agency (DTRA), has been active in reducing the threat of proliferation of Weapons of Mass Destruction (WMD) materials, expertise, and associated delivery systems in the former Soviet Union (FSU) for the past 2 decades; it employs and monitors scientists who conducted research in support of the Soviet offensive nuclear and biological weapons programs. Through DTRA, the USG also has worked with host nations in the region to significantly expand clinical diagnostic capacity by funding the construction of modern laboratory facilities in Georgia and Kazakhstan.¹² Recent NAS reports have called upon DTRA to expand the CTR program to include countries outside the former Soviet Union and additional efforts aimed at improving international disease surveillance capacity.^{2,3}

The Global Emerging Infections Surveillance and Response System (GEIS): This program links DoD laboratories, research facilities, and the military health system to protect armed forces through rapid recognition of and response to health threats. Established in 1997, GEIS conducts clinical and laboratory surveillance for emerging infectious diseases and for routine outbreaks of influenza, other respiratory diseases, enteric diseases (such as norovirus), acute febrile illness (such as malaria), acute hemorrhagic fevers (such as dengue), antibiotic resistant microbes, and sexually transmitted diseases.¹³



FINDING 1: The existence of multiple major U.S. goals for international disease surveillance requires distinct USG approaches.

The Center identified the following 5 goals of USG international disease surveillance efforts:

1. Bolster overall public health capacity of other countries to help them assess the impact of endemic diseases and differentiate outbreaks from endemic disease.
2. Obtain early warning about outbreaks of human disease.
3. Predict future human disease threats by monitoring zoonotic disease outbreaks and diseases that circulate within animal populations.
4. Obtain information to help maintain situational awareness during response to an epidemic in order to facilitate response.
5. Fulfill U.S. obligations under the IHRs to assist other countries in developing the capacity to detect, report, and respond to public health emergencies of international concern.

Each of these 5 USG agency goals requires collection of specific types of data and mandates distinct approaches to information gathering and analysis. In some instances, USG agencies have required highly specific data from international sources and employed specialized surveillance systems that did not interface with other disease surveillance systems in the same agency or in other agencies. There also has been considerable overlap in USG agency international disease surveillance goals—for instance, a number of agencies maintain programs directed at influenza surveillance.

The information collected and analyzed by each USG agency can differ greatly as the 5 goals are pursued. For example, the challenge of assessing trends in high-burden diseases that are known and occur

frequently are quite distinct from the surveillance challenges of detecting rare diseases against a background of endemic disease. The information requirements and approaches for each of those goals may differ considerably depending upon the disease and the host country in question.

Each USG agency also varies in its requirements for speed of data collection and data fidelity.¹⁴ For example, some agencies emphasize collection of scientifically sound, confirmed, or vetted information, while others attend most closely to unconfirmed media reports or rumors. Agency-specific information needs may also vary with time, depending upon the specific demands of a particular event. For instance, the H1N1 influenza pandemic in 2009 prompted implementation of new surveillance systems capable

of gathering data that were more specific than those collected by existing systems because U.S. political leaders had greater information needs during the acute phase of the crisis.¹⁵

Below is a description of the 5 goals, including several of the notable complexities in efforts to meet them.

GOAL 1: BOLSTER OVERALL PUBLIC HEALTH CAPACITY OF OTHER COUNTRIES TO HELP THEM ASSESS THE IMPACT OF ENDEMIC DISEASES AND DIFFERENTIATE OUTBREAKS FROM ENDEMIC DISEASE.

A primary goal of USG international disease surveillance efforts is to support traditional public health surveillance activities. This requires coordination of many different programs at local, national, and global levels. USG efforts to assist in routine disease surveillance may range from providing technical support to a host nation's ministry of health, or establishing laboratory capacity in resource-limited settings, to establishing community-level programs to train lay persons to recognize and report cases of specific diseases. Traditionally, these surveillance efforts have been organized around specific diseases or syndromes, such as malaria, tuberculosis, and HIV.

The information obtained from these efforts is used for a variety of purposes. First, the CDC may use these data to determine what risk, if any, these diseases pose to the U.S. population. Next, this information may be used to determine where the USG should focus its resources and to evaluate whether control programs such as risk communication campaigns, vaccination campaigns, or other public health interventions are effective or whether they need to be applied in a different way.

Finally, having a robust detection capability for endemic disease may make it easier for public health authorities to also detect the occurrence of an unusual or unexpected disease event discernible to public health authorities. For instance, the

detection of an influenza pandemic or an outbreak of anthrax would be much more difficult if the usual rates of respiratory illness in an area were not well characterized, since an outbreak of anthrax or novel influenza would be observed as an increase in nonspecific respiratory illness beyond background or expected rates.

*"You have to make a determination based on seasonality and based on resistance profile of whether something is a normal pathogen and normal clinical presentation or something else."***

"To be able to determine normal, unusual, background noise, you need to have a system that can analyze data historically and be able to establish some thresholds."

The U.S. may experience indirect benefits in helping other countries improve surveillance of routine public health threats.¹⁶ Some participants suggested that professional relationships established between U.S. and international scientists and health authorities as a result of collaboration on routine public health surveillance programs may prove to be beneficial in investigating and responding to other kinds of public health threats.

"There's a hearts and minds component, a global network building component and a diplomatic piece, that if we do it right, overlays all of these other goals."

Participants asserted that, regardless of the primary purpose of surveillance, the information collected should be tied to public health actions and interventions, because an assured public health benefit may improve compliance with data collection and information sharing. Experts noted that data providers often feel more invested in collecting and relaying surveillance data if they are able to see that authorities use their data to take action. In addition, without a recognizable benefit, such as access to

**Quotes that appear in italics throughout this report are from experts who participated in this project. For a complete list of project participants, see Appendix A, page 23. The Center conducted all conversations with experts on a not-for-attribution basis.

vaccines or medicines, some host countries may choose not to identify and make public information pertaining to disease rates, which could result in decreased tourism and/or trade restrictions.

"Governments will say, 'What is the point of counting cases when we have no medicines to give people?'"

GOAL 2: ACHIEVE EARLY WARNING ABOUT OUTBREAKS OF HUMAN DISEASE.

U.S. efforts in international disease surveillance have a second goal of achieving early warning about outbreaks abroad. There are a number of reasons for this: (1) to provide host countries with early information needed for response; (2) to prepare for response to subsequent outbreaks in the U.S.; (3) to protect U.S. citizens abroad, including troops; (4) to detect biological weapons programs; and (5) to detect bioweapons attacks.

"If we had detected H1N1 a few months earlier, we could have incorporated it into our seasonal vaccination effort, which would have helped things a great deal."

"It will be very hard to tell if an epidemic is deliberate; therefore, [U.S. agencies] may have to be more interested in monitoring an outbreak from the beginning because we won't know for sure if it's a security concern or not."

Since 2001, increased interest in systems for early warning has sparked development of a number of different approaches to early detection of disease outbreaks; however, there is no broad consensus on which systems work best for this purpose.⁴ A variety of systems are currently in use, including those that: scan news media sources for reports of disease outbreaks; track increases in the purchase of specific over-the-counter medications or in the numbers of people who present to healthcare providers with specific syndromes, such as rash; and monitor and analyze trends in internet searches for medically relevant topics.

Consideration must be given to the feasibility of implementing early warning detection systems

in areas where staff is limited or where traditional public health surveillance systems are weak, as even though these systems are largely computer-based, they still must be managed by experienced human analysts. Early warning systems often rely on statistical algorithms to determine when surveillance data are unusual or unexpected; additional epidemiologic investigation of statistical signals is usually necessary to determine whether an alert has any public health significance. In most areas where early warning systems are deployed, the first step taken by public health authorities in response to an alert is to compare system data with data from other public health surveillance systems. Experts noted that while alerts generated by early warning systems may ultimately be found to be of little or no concern, time and resources must be devoted to determining whether statistical alerts are of public health significance.^{4,17,18,19}

"Most of the signals we pick up don't turn out to be anything. We can't call up countries 10 times a day and ask what's going on."

"It's hard to build a new system in a developing country to look for the 'I don't know.'"

GOAL 3: PREDICT FUTURE HUMAN DISEASE THREATS BY MONITORING ZOONOTIC DISEASE OUTBREAKS AND DISEASES THAT CIRCULATE WITHIN ANIMAL POPULATIONS.

USG international disease surveillance programs have a third major goal: detecting zoonoses or human cases of diseases that historically have been confined to animal populations. In recent years, the vast majority of emerging infectious disease events has been the result of mutations in wildlife pathogens that have allowed infection of human hosts.²⁰ Prime examples include the 2003 severe acute respiratory syndrome (SARS) epidemic and the 2009 H1N1 influenza pandemic.

There are clear tangible benefits to monitoring animals for possible human pathogens. For example, one of the project participants noted that it would be possible to detect West Nile virus in horses weeks

before the first human case presented, giving public health authorities valuable lead time to develop intervention strategies.²¹ There was strong consensus among the experts that monitoring animal diseases may provide important data for future human outbreaks (eg, H5N1 influenza, West Nile virus, SARS).

However, despite expert consensus on the potential benefits of improved zoonotic surveillance, the Center found a number of barriers to meeting this goal, including considerable economic deterrents to reporting animal disease, especially in agricultural herds. For instance, during the H1N1 influenza pandemic, without any scientific justification, several countries banned pork imports from countries that reported human cases of H1N1.²² Another barrier is lack of human and financial resources. Agencies typically charged with animal health surveillance, such as agriculture or wildlife ministries, often do not have the resources needed to carry out disease surveillance at the human/animal interface and are poorly suited to the task of determining the potential threat to humans posed by animal disease.

"There are strong economic disincentives to agricultural surveillance."

"Our [agriculture and wildlife] agencies are focused on domestic missions and underfunded for international work."

"Wildlife agencies generally lack the right skill sets (eg, veterinary pathologists). They are more interested in ecological effects."

As a result, resources currently deployed to monitor animal health are not sufficient for surveillance of zoonoses.

GOAL 4: OBTAIN INFORMATION TO HELP MAINTAIN SITUATIONAL AWARENESS DURING AN EPIDEMIC.

A fourth goal of international disease surveillance systems is to obtain data necessary for maintaining the situational awareness needed to manage epidemics once they are detected. Situational

awareness—the ability to monitor progress of an outbreak, determine where to deploy resources, etc.—requires access to the information needed to make key decisions in a timely fashion. It depends upon collection of the right information, skilled analysis, and rapid delivery to those who have to act upon the analysis. Examples of the types of information needed to manage the epidemics and outbreaks include:

- Is the outbreak getting bigger or abating?
- Is the virus mutating? Is it causing more severe illness?
- What kind of public health and medical resources are available? Where are they?
- To whom do we give vaccines and medicines? If there's not enough for everyone, how will priority groups be located and identified?
- How do public health and medical providers stop the spread of infection and care for the sick?

Although traditional public health surveillance systems may provide answers to some of these questions, the answers to many may exist outside of traditional systems. For example, during the H1N1 influenza pandemic, authorities wanted to know how fast the virus was being transmitted and how many people a sick person would infect. To get answers to those questions, staff at New York City's Department of Health and Mental Hygiene conducted dedicated investigations using an internet-based survey tool to query the students and staff at a school where cases were occurring.²³

Maintaining situational awareness during epidemics may require better integration of available data sources originating from different organizations, agencies, or governments.²⁴ Data from nontraditional data sources, such as unconfirmed reports from event-based reporting systems (eg, ProMED), may comply with confirmed public health data from official reporting systems.

"It is important to bring together routine surveillance information with event-based surveillance"

information to complement the information that is being received from health centers/facilities."

Maintaining situational awareness during outbreaks often also requires sharing of data between levels of government or among agencies. During the 2009 outbreaks of H1N1 influenza, the response of individual countries depended upon analysis of data obtained from other countries.²⁵

"We were severely challenged during H1N1 in our abilities to receive epidemiological data to be able to know if the virus was mutating as it moved around the world."

Finally, situational awareness may require a better exchange of data between public health and clinical sectors, as critical data may also exist in the healthcare sector.²⁶ For example, knowing more about the underlying conditions of some of the first patients to succumb to H1N1 in Mexico may have provided a more accurate picture of the virus's lethality. Unfortunately, patient data are not typically captured in traditional public health surveillance programs. It will require separate, dedicated efforts to get access to clinical information during future infectious disease emergencies.

GOAL 5: FULFILL U.S. OBLIGATIONS UNDER THE INTERNATIONAL HEALTH REGULATIONS TO ASSIST OTHER COUNTRIES IN DEVELOPING THE CAPACITY TO DETECT, REPORT, AND RESPOND TO PUBLIC HEALTH EMERGENCIES OF INTERNATIONAL CONCERN.

Under the revised IHRs of 2005, the U.S. and other nations have a statutory obligation to help resource-constrained countries develop or strengthen their ability to detect, report, and respond to public health events of international concern (PHEICs).⁶ In addition to fulfilling its legal obligations, the U.S. has a strategic interest in helping countries improve recognition and reporting of acute public health threats. This was apparent during the 2003 SARS epidemic, when global response was delayed by China's failure to report early cases of the new disease.²⁷

Global interest in meeting IHR obligations is prompting a fair amount of disease surveillance activity.²⁸

"The IHRs are being viewed as the beginnings of a standard operating procedure for what international disease surveillance data can/should be shared between countries."

Public health infrastructure often is neglected in both wealthy and poor countries.²⁹ The IHRs may be motivating to political leaders who otherwise might not give priority to improving disease surveillance capabilities. There was strong consensus among project participants that the revised IHRs represent an important opportunity to try to engage with other countries to improve global disease surveillance capacities. Many participants thought countries that previously would not have prioritized the need to strengthen surveillance for acute or rare diseases now may be more inclined to do so in order to remain in good global standing. Additionally, some participants noted that the IHRs may enable the U.S. to engage with countries in ways that previous efforts made under the umbrella of security would not allow. Countries that may not have wanted assistance from the U.S. for the purpose of strengthening security may be willing to accept assistance for the purpose of meeting their IHR obligations.

However, it was also noted that there may be some shortcomings in using the IHRs as a rallying point for greater U.S. engagement in international disease surveillance. For example, the IHRs emphasize public health risks that are unexpected or unusual and that have the potential to threaten other countries. As a result, some experts thought that even with the IHRs' statutory obligations, countries that experience a high burden of endemic infectious disease may not prioritize the need to invest in detection and response to rare or acute events when they are not able to meet the challenges associated with controlling routine diseases within their own borders.

Some participants also expressed skepticism that the U.S. should attempt to attain certain security goals under the rubric of IHRs. These participants stressed that countries that signed on to the IHRs did so under the agreement that the IHRs were to be used for public health purposes only and not for security. For example, one participant noted that Iran agreed to the IHRs after receiving explicit assurance that they would be used only for public health and not for security purposes.

Still unanswered are some questions about the operational requirements of achieving compliance under the IHRs. For instance, the specific actions required of the USG to meet its obligations to help other countries achieve IHR compliance are not clear. Although countries are completing and submitting to the WHO assessments of their capacity to detect and

respond to PHEICs, it is not clear that these capacity assessments will be made public. Project participants expressed concern that this could make it difficult to identify the steps needed to improve disease surveillance capacity on an international basis. It was suggested that the WHO should make available a description of resource needs by region to facilitate identification of areas of need for those countries willing to provide assistance.



FINDING 2: Targeted USG investment could strengthen international disease surveillance.

The Center's analysis indicates that these 5 initiatives could improve the USG's ability to pursue and achieve the disease surveillance goals noted above:

1. Increasing the number of trained in-country personnel
2. Developing flexible tools for information acquisition and analysis that promote communication between public health and healthcare professionals
3. Improving surveillance for zoonoses by incorporating collection and analysis of animal health data into human health surveillance programs
4. Improving laboratory and diagnostic capacity to detect and characterize important pathogens
5. Developing surveillance systems that meet routine surveillance priorities of host nations and provide for surveillance of emerging infectious diseases and other health security threats

1. INCREASING THE NUMBER OF TRAINED IN-COUNTRY PERSONNEL

Project participants largely agreed that a lack of skilled public health personnel poses a tremendous challenge to information collection, analysis, and response. Globally, there is a significant shortage of in-country personnel who are well trained to work either in diagnostic laboratories or as public health epidemiologists.³⁰

"You can't develop a disease surveillance system in a country without trained people."

There was strong interest in expanding efforts to train individuals in host countries, particularly in the fields of laboratory diagnostics, epidemiology, veterinary medicine, and biosafety. Successful

training programs would also enhance management skills and analytic abilities of in-country surveillance professionals.

"Training efforts should be structured in such a way to encourage that capacity to stay in the local system."

To be most effective, training efforts should build on existing programs that are addressing critical personnel shortages. One such effort is the CDC's Field Epidemiology Training Program (FETP) and Field Epidemiology Laboratory Training Program (FELTP). Started in 1980, the FETP/FELTP effort was modeled after the CDC's Epidemic Intelligence Service, to help other countries improve public health surveillance and outbreak response programs.³¹ The

2-year FETP program provides in-country personnel with classroom and field instruction in epidemiology, communications, economics, and management. The FELTP provides training in those same areas, as well as in laboratory surveillance. To date, the combined programs have produced more than 1,000 graduates.³¹

However, the Center's review identified several perceived weaknesses in existing training programs. One concern is that donor countries may view training efforts as expensive relative to the number of individuals they train. Another is that program success varies by location in that it depends upon available local capacities at the outset of a program and the investment a country is willing to make to ensure continued support.

"Although training efforts have been very effective in Thailand, the FETP in Indonesia has really not blossomed and been a success."

Another concern voiced by experts is that of "brain drain." Skilled surveillance personnel are often able to acquire better-paying jobs abroad, which defeats the purpose of in-country training.

"You train a lab technician in West Africa and you've just given him a skill set that will allow him to emigrate into a much higher paying country. As we train and give the individuals the skills, they have a tendency to move around and market their skills away from the public health sector that they're originally in. So you can't assume that once we train 80 epidemiologists in Argentina, now they have 80 epidemiologists in Argentina. You've got to continually do it so that next year there are still going to be 80 there."

However, there are efforts to combat brain drain—the Fogarty International Center, for example, maintains a program that trains personnel in developing countries and makes "return agreements" and offers re-entry grants to encourage trainees to return to their home countries.³²

2. DEVELOPING FLEXIBLE TOOLS FOR INFORMATION ACQUISITION AND ANALYSIS THAT PROMOTE COMMUNICATION BETWEEN PUBLIC HEALTH AND HEALTHCARE PROFESSIONALS

While project participants broadly agreed that flexible tools are needed to promote and support information acquisition, analysis, and communication, they also agreed that no single tool can help meet all major USG biosurveillance goals.

"We can't achieve all of our goals with the same system. If we truly want to meet all of these objectives or goals, we have to think in terms of multiple approaches and potentially different approaches tailored to meeting different goals."

Because the types of information needed to detect and manage an outbreak (and other public health emergencies) are specific to a particular event, the tools for disease surveillance must be flexible and adaptable to meet changing needs. To that end, participants recommended that new systems be field-tested as part of the development process to assess the degree to which they meet users' needs. Testing is also required to ensure that implementing event-specific changes to a surveillance system will not require highly specialized expertise or considerable time or money.

To assess disease patterns and severity and to improve patient care, flexibility is also needed in tools that facilitate communication and data exchange between healthcare and public health agencies. The importance of the clinical sector in detecting and managing disease outbreaks was demonstrated during the 2009 H1N1 pandemic. This was particularly true very early in the outbreak when severity could not be determined because it was not possible to determine whether young and healthy patients who were hospitalized or died had important underlying medical conditions.³³ Had patient data been available, public health authorities would have been able to determine disease severity and plan response accordingly.

"History has proven time and time again that astute clinicians are the ones who actually identify these new diseases."

"Most disease surveillance efforts fail to provide information back to the clinical sector to improve care of patients."

In many areas, patient data are not captured in traditional public health surveillance programs; therefore, separate, dedicated efforts to access clinical information during future infectious disease emergencies are required.³⁴ This may be particularly true in areas where the majority of individuals seek clinical care outside of public healthcare systems.³⁵ For example, one participant noted that in some areas of Southeast Asia, 80% of all healthcare visits are to private clinicians or to alternative or traditional-medicine healers. In those and similar settings, surveillance systems that rely on data from public systems would miss a large fraction of clinical cases.

"In H1N1 we saw that many cases were going to private healthcare institutions, so surveillance was difficult because private healthcare and private laboratories are not integrated in the public system. Traditionally, omitting private healthcare from surveillance efforts has not been a big issue, as many diseases tend to disproportionately affect the poor. But as we saw during H1N1, that is not always the case with emerging infections."

Because needs assessment is a critical first step in tool development, the USG should not approach partner countries with a particular tool or technology in hand; instead, new surveillance systems should be developed only after specific user needs are determined. Needs assessment should be completed prior to any systemic deployment and should involve all stakeholders, including the lead agency and host country's ministry of health. Once deployed, the effectiveness of surveillance tools should be evaluated continually through exercises and after-action reports following real infectious disease events. Such efforts may increase ongoing systemwide buy-in, without which a new technology or surveillance system will likely fail.

"Do not lead with a technology solution. It's better to go in with a blank slate and learn what would be helpful to users before designing a surveillance system."

Project participants offered several examples of tools that did not meet local needs, including implementation of software and computers in areas that did not have consistent electricity and internet connections, and provision of computers without disc drives or USB ports, making it impossible for users to share data with colleagues.

"Whether or not a surveillance system will work may not always be because of the technology itself. There are facilitating factors that are important. For example, if you require the internet for the system to work, then you have to have reliable internet connectivity. You also have to have people who are trained to use the system."

Project participants stressed that in many cases, the most successful surveillance programs were those that enabled the development of relationships and collaboration and communication among workers in different parts of government or in different organizations. Interoperability with existing systems is essential to prevent duplicative effort. Participants suggested that frameworks such as the Health Metrics Network³⁶ and the Routine Health Information Network (RHINO)³⁷ may be useful in designing and developing systems capable of communicating and integrating information across various sectors.

"The development of pre-existing relationships and social capital are even more important than technology—people share data across borders because they have trusted colleagues."

"There should be greater emphasis on open source systems and integration of information. There are often a plethora of systems within a country that do not talk to one another."

3. IMPROVING SURVEILLANCE FOR ZOONOSES BY INCORPORATING COLLECTION AND ANALYSIS OF ANIMAL HEALTH DATA INTO HUMAN HEALTH SURVEILLANCE PROGRAMS

Since 1950, nearly two-thirds of infectious disease outbreaks have been caused by zoonotic pathogens (diseases that can be transmitted between humans and animals), resulting in economic losses of more than \$200 billion worldwide in the last 10 years alone.³⁸ Despite the significant threat posed by these diseases, worldwide zoonotic disease surveillance is severely lacking.

"I'm constantly surprised by our being okay with using humans as sentinels when the majority of the diseases, particularly those that have security implications, originate in animals. In most of the countries where we are working to improve surveillance for security purposes, the veterinary side is almost completely unable to detect very basic infectious diseases."

Project participants stressed that more work is needed to ensure collection of appropriate animal health data. They also noted that international surveillance programs must be staffed by individuals with skill sets broader than those required for human disease surveillance.

"You need multidisciplinary teams to tackle zoonotic diseases. This includes a wide range of stakeholders, including environmental health, toxicology, and ecology experts that should be included in developing surveillance systems."

Improved surveillance for zoonotic diseases will also require better integration of human and animal health surveillance data systems. Some promising efforts to co-locate human and animal health laboratory research may serve as possible models for future zoonotic surveillance. For example, the Canadian Science Center for Human and Animal Health, a state-of-the-art BSL-4 laboratory in Winnipeg that is jointly operated by the Public Health Agency of Canada and the Canadian Food Inspection Agency, was created to better integrate human and animal surveillance. Animal and human health laboratories

were co-located to encourage collaboration between researchers in the 2 areas.³⁹

Participants also noted that CDC's ArboNET, the U.S. arboviral disease surveillance system may also serve as a model for surveillance of zoonoses. Developed in 1999 after the first cases of West Nile virus in the Western Hemisphere occurred in New York City,⁴⁰ ArboNET transmits data from mosquito and bird virology data to state and national human and animal health authorities. The information is used to help guide mosquito control programs and public health risk communication.³⁸ Project participants noted that, although additional work is needed to strengthen the veterinary health and other components of ArboNET, the program represents positive progress in efforts to integrate human and nonhuman data sources.

Project participants also noted 2 barriers to improvement of zoonotic disease surveillance: inadequate political support in the U.S. and in other countries and insufficient funding. Countries may maintain agencies responsible for either human or animal health, but if surveillance for zoonoses is not within an agency's mission, then the organization may not be willing to lead national efforts to integrate surveillance at the interface of human and animal health.

"No one owns zoonotic surveillance. Agriculture ministries are usually primary agencies for 'herd' health, but often don't have within their mission the investigation of zoonoses."

Sufficient funding is required to conduct surveillance in wildlife and in pets, both areas critical to detection of zoonoses. One participant noted that while the vast majority of zoonotic diseases originate in wildlife, wildlife agencies are generally restricted to studying population effects and do not have as part of their mission the identification of pathogens that may infect humans. Similarly, while there has been documented human infection from pets, such as an outbreak of monkeypox in Wisconsin that began in pet Gambian rats,⁴¹ few programs exist for zoonotic disease surveillance among pets.

"You only find out about a disease outbreak if somebody makes a diagnosis. That means somebody has to pay for it. It's not necessarily going to be some pet owner. It's also not going to be some pet shop owner."

"Veterinary agencies are agricultural based. They look at animals of economic importance. They're not looking at the dogs and the cats and the squirrels and the little chipmunks and all the things that would serve as urban biosentinels. Animals that are close to people are not anyone's responsibility."

4. IMPROVING LABORATORY AND DIAGNOSTIC CAPACITY TO DETECT AND CHARACTERIZE IMPORTANT PATHOGENS

An important component of a disease surveillance system is the collection, analysis, and laboratory confirmation of clinical specimens to determine disease etiology.⁴² In recent years, experts have called for the development of rapid, field-deployable diagnostic tools that can provide confirmation of disease without the infrastructure needed to support sophisticated laboratories.⁴ Rapid and reliable point-of-care diagnostic tests would help in the control of outbreaks by enabling clinicians and public health practitioners to identify ill persons quickly and to help isolate them from persons who are well.

However, even with the increasing availability of field-deployable diagnostic tools, laboratory confirmation will still likely be required. Rapid diagnostic tools may not provide adequate information for pathogen characterization and other data important to determining outbreak response.^{38,43} As demonstrated during the 2009 H1N1 influenza pandemic, rapid point-of-care flu tests, which are used increasingly to diagnose and manage influenza, were prone to high levels of false negative reports.^{44,45} Such performance limitations put increasing pressure on clinical and public health laboratories.⁴⁶

"Surveillance systems may generate 'signals,' but you need a laboratory component to identify the pathogen."

"In the [2009] H1N1 outbreak, we found that there was inadequate capacity for accurate rapid diagnostic testing. Rapid antigen tests were unreliable. PCR was not available in many clinical labs . . . laboratories had difficulty keeping up with the volume of tests."

Project participants noted the urgent need to enhance international laboratory capabilities to detect and characterize epidemics, particularly those caused by emerging infectious diseases.

"We are far worse in our ability to identify an unknown today than we were 20-30 years ago."

Despite widespread agreement that enhanced laboratory capacity is needed, there were differences in views among project participants regarding the preferred approach to strengthening laboratory capacity. Two general approaches to enhancing laboratory capacity emerged in the study. The first approach is to build a focused lab capacity in which labs are designed solely to identify specific threat agents. The techniques used in these labs mainly would utilize molecular techniques with inactivated biological samples (eg, PCR assay kits). This method is preferred by those who wish to minimize development of general microbiological capacity that could be dual-use and that would also require storage of biothreat agent isolates. One potential advantage to this approach is that, due to the application of simplified technologies, operation may require less training. It has been recognized that traditional microbiological laboratories are complex facilities that are expensive to build and maintain, and it may be beneficial to be able to "swap" in new molecular technologies for detecting new pathogens.

"You can accomplish a lot of what people want to accomplish without giving them a BSL-4 facility."

"Not every district in every country needs to be able to do state of the art virology."

The second approach to building lab capacity, favored by some participants, encourages the establishment of broad microbiological capability, with labs equipped for proficiency in classical

microbiological methods, including culture and serology, to complement molecular assays. Those in favor of this more expansive lab capacity argue that laboratorians in much of the world may be more familiar with traditional, culture-based microbiological techniques than with molecular-based approaches. Consequently, these labs would be more valued by in-country health officials, because they would help serve routine purposes.

"In most developing countries, what people know and what they've been trained on is classical microbiology—bacteriology and virology—and that's the cheapest way that they know how to identify things. We can bring a lot of great technology, but we need to think about what's sustainable and what's not."

Supporters of expansive lab capacity also note that laboratories that employ only molecular-based diagnostic techniques would at some point require challenge with live agents in order to maintain quality control/assurance in the laboratory. Supporters were not particularly concerned about issues of proliferation (ie, providing live agents to foreign laboratories), because these pathogens exist in nature or in other labs or repositories in the world, making it difficult, if not impossible, to stop a determined effort to acquire them. And since most modern molecular assays, such as PCR, require prior knowledge of a pathogen's relevant characteristics, traditional techniques might be of greater use in detecting and identifying unknown diseases for which molecular assays do not yet exist. Additionally, allowing access to more advanced laboratory capacities may demonstrate U.S. commitment to a host nation's emerging public health capacity.

"Using PCR kits and the like is guaranteed to fail in looking for new emerging diseases."

Finally, supporters of disseminated, expansive laboratory capacity argued that it could reduce delay or degradation of samples associated with sending samples to reference labs abroad for additional testing.

5. DEVELOPING SURVEILLANCE SYSTEMS THAT MEET ROUTINE SURVEILLANCE PRIORITIES OF HOST NATIONS AND PROVIDE FOR SURVEILLANCE OF EMERGING INFECTIOUS DISEASES AND OTHER HEALTH SECURITY THREATS

The Center's analysis found strong support for building capacity to detect and respond to routine public health threats as the foundation for enhancing a country's capacity to handle rare events. If a country's system surveys only for a list of specific, rare pathogens and does not regularly exercise overall surveillance capabilities, it may not be effective in identifying a new pathogen, or even a pathogen on the list. Participants suggested that, upon entering into an assistance role with a host nation, the USG should work with representatives of the host country to conduct a needs assessment that identifies local surveillance priorities. In helping develop a country's ability to detect, report, and respond to routine public health threats, the USG can create a baseline level of practice and then help develop the ability to handle rare events. Such an approach may afford the USG an opportunity to incur goodwill while advancing its international disease surveillance goals.

"Start small. Work on the issues that the country wants to deal with, then apply the system to other diseases."

"The only way for a country to become proficient at responding to more exotic outbreaks is to first become capable of dealing with more common pathogens, like TB or measles."

"Start with specific goals; after core capacity and trust are developed, then the systems could be expanded to a broader mission."

"Countries are happy to have the resources that often come with USG foreign aid programs, but become frustrated when they find that programmatic aims don't address more common infections in their country."

Although this analysis found little support for requiring that countries focus solely on biothreat diseases, at least at the onset of a program, opinions about ways to identify routine disease surveillance priorities differed. Individual countries could be given the opportunity to determine their own surveillance priorities, which can then be expanded to include USG priorities once overall public health capacity is improved. Supporters of this approach felt that host countries may be more inclined to accept assistance from the U.S. if they are allowed to determine their surveillance priorities rather than being required to conduct surveillance for a list of diseases that are of interest only to the USG.

Alternatively, disease surveillance priorities could be decided on a regional rather than a country-by-country basis. For example, several countries in a region could be given the opportunity to select a disease that affects all and then work together to build a surveillance system. This approach could provide the ability for multi-country collaboration on detection of and response to a common pathogen. A number of project participants felt that the development of regional collaborative relationships would contribute greatly to global response capacity for PHEICs.

While this analysis found that it is important for countries to build surveillance capacity by starting

with local priorities, it is likely that local priorities would not include many diseases that are of interest to the USG (see Table 2, below). Benefits of addressing local priorities (ie, having a routinely exercised system for which countries have a sense of ownership) would likely outweigh the downsides of this approach, but USG agencies would have to be able to make a convincing case to funders (ie, the U.S. Congress) showing how investment in surveillance for routine disease (eg, rotavirus) prepares countries to detect and respond to rarer events like pandemic influenza or emerging infectious disease.

"If the [partner country's] priorities are going to be towards the important endemic diseases, many of the diseases that the U.S. cares about internationally, such as influenza, would fall off the radar screen, because they simply wouldn't be important by local standards as a cause of death or disease. So I think it's a challenge for us to align those priorities on a global basis to make sure that both local and global priorities are being met."

"In some cases we said, 'If you'll do this, we'll do this for you.' And then we moved the goalposts. And eventually Vector [the former Soviet biological weapons lab] was working with France and Germany more than they were working with us, and they still have stronger relationships with them than they do with us."

Table 2: Comparison of the types of diseases that are on the U.S. National Select Agent Registry vs. those that may constitute public health events of international concern (PHEICs) vs. those that may cause high levels of mortality and morbidity in the developing world.

Examples of Diseases that are on the U.S. National Select Agent Registry ⁴⁷	Examples of Public Health Emergencies of International Concern ⁶	Examples of High-Burden Endemic Diseases ²⁹
Smallpox	Smallpox	HIV / AIDS
Reconstructed 1918 Influenza virus	Novel Human Influenza	Tuberculosis
Anthrax	Severe Acute Respiratory Syndrome (SARS)	Malaria
Viral Hemorrhagic Fevers (Lassa, Marburg, Ebola)	Viral Hemorrhagic Fevers (Lassa, Marburg, Ebola)	Rotavirus



FINDING 3: Potential opportunities exist for improving USG implementation of international disease surveillance programs.

The following actions, discussed in detail below, represent opportunities for USG agencies to improve implementation of U.S. international disease surveillance programs:

1. Improve coordination among USG agencies involved in international surveillance
2. Improve USG coordination with foreign governments and NGOs involved in disease surveillance
3. Address international perceptions of military/intelligence/commercial use of disease surveillance data

1. IMPROVE COORDINATION AMONG USG AGENCIES INVOLVED IN INTERNATIONAL SURVEILLANCE

There is currently no overall federal strategy to guide or coordinate the international disease surveillance efforts of USG agencies. There was consensus among project participants that the absence of a common strategy—or at minimum, a means by which to coordinate—hinders agencies' abilities to guide the development of new programs, to prioritize funding of disease surveillance activities, and to coordinate activities with other agencies that may be engaged in disease surveillance activities in the same country. Improved communications between U.S. agencies, particularly at the early stages of planning, was identified as critical to avoiding duplication of efforts, as well as to ensuring that agencies are not working at cross-purposes.

"If there are 2 or more USG agencies working in the same region, there is no formal way for them to work together as a common team and no

performance or funding incentives to promote such collaboration. Currently, interagency cooperation in host countries is dependent on informal relationships between personnel on the ground."

"If I was king of the world, I would put together an interagency working group to coordinate USG goals."

Lack of U.S. interagency coordination was also something that the National Biosurveillance Advisory Subcommittee identified as a key hurdle for U.S. disease surveillance efforts. The NBAS issued a report in 2009 that called upon the USG to develop a comprehensive strategy for disease surveillance and to improve coordination of efforts among U.S. agencies.⁴ The NBAS proposed that the White House create an Interagency Disease Surveillance Coordination Committee, which would be chaired by an official from the Executive Office of the President and which would work to coordinate U.S. policy on disease surveillance, including international disease surveillance.

Project participants generally agreed that interagency coordination would be likely to help improve coordination of USG efforts in disease surveillance. Some participants objected to one suggestion offered by the NBAS—the designation of a lead federal agency for disease surveillance—fearing that a single federal lead would create turf battles, given the diversity of disease surveillance missions. Other experts agreed that having an interagency process for coordination on disease surveillance is more important than designating a lead USG agency for international disease surveillance.

2. IMPROVE USG COORDINATION WITH FOREIGN GOVERNMENTS AND NGOs INVOLVED IN DISEASE SURVEILLANCE

The Center's analysis also found that improving global disease surveillance was slowed by coordination challenges that arise among multiple governments and NGOs working in the same country or regions, with overlapping interests in improving surveillance capabilities. Participants cited specific examples to show how insufficient coordination at the international level can jeopardize efforts to improve surveillance at the national level.

First, available collective resources are not distributed as effectively as they could be if there were better coordination. Experts said that in some cases host countries receive so many offers of assistance from foreign governments or NGOs that they are unable to accept aid because they do not have the resources to determine which offers are worth accepting and which ones are not. At the same time, other countries with similar disease risks may receive far fewer offers of assistance and would be very willing to accept aid.

Second, there are many overlapping and non-interoperable disease surveillance systems. When multiple governments or NGOs establish surveillance programs with specific goals in a country, this can result in development of parallel, but noninteractive, surveillance systems. One expert recounted a story in which workers in a rural health clinic had to enter

the same data into 3 different surveillance systems because each donor required information in a unique way. Although the systems gathered the same information, the worker in the understaffed clinic had to spend a considerable amount of his time performing the same job 3 times over. This led to frustration among the data providers, who began to question the reason for participating in the programs at all, as the data reporting requirements began to interfere with patient care.

Coordination at the regional or international level may help ensure greater coverage, reduce duplication, and increase the desire to share information.^{48,49}

"Going forward, some groups may have to give up on their specific interests. Instead of encouraging disease siloing, they should allow for the establishment of more integrated systems."

"Hundreds of people are looking for viruses in bat guano, but mosquitoes, ticks, rodents, and other vector-borne pathogens are practically ignored."

"Working in networks makes it easier to assess the needs of countries or to determine which offers are important to accept—this is very important to getting programs off the ground."

3. ADDRESS INTERNATIONAL PERCEPTIONS OF MILITARY, INTELLIGENCE, AND/ OR COMMERCIAL USE OF DISEASE SURVEILLANCE DATA

A number of participating experts conveyed that some countries have concerns about how their surveillance data will be used. Although there may be a number of reasons why countries may not want to work with the U.S. on disease surveillance, experts cited countries' reluctance to provide disease surveillance data if those data are used for intelligence purposes or for commercial gain as a common reason.

Therefore, cooperation with U.S. international disease surveillance efforts may be jeopardized if partner countries perceive U.S. disease surveillance efforts to be for purposes other than public health.

The recent closure of the Naval Medical Research Unit 2 (NAMRU-2) in Indonesia is an example of what happens when a partner perceives that the U.S. military and/or western corporations are profiting from its data—whether those perceptions are accurate or not. The nature of the disagreement between the U.S. and Indonesia is complex, but it was noted that Indonesia's complaints have resonated with other countries, which have, as a result, started reevaluating their relationship with U.S. labs. Project participants suggested that preservation of collaborative scientific and public health relationships, particularly in strategically important areas, is important to maintaining global health security.

"Countries perceive military-led disease surveillance efforts as intelligence-gathering operations."

"A number of countries share deep concerns that western corporations will profit from their clinical samples."

Several participating experts stressed that countries' concerns will be exacerbated if U.S. agencies are seen to be trying to extract data from host countries. To that end, it could be problematic to require public health data be transferred to the U.S. as part of any international disease surveillance program, as it could raise suspicions that the USG is using those data for military, intelligence, or commercial purposes. Experts suggested that USG agencies focus instead on building trusting, professional relationships that may over time lead to the voluntary sharing of disease surveillance data by host countries.

"We have to move toward a model of building capacity and hoping that countries share information, rather than building systems to collect information."

"The establishment of a data repository within the U.S. is detrimental, as it reinforces the perception of U.S. assistance as an intelligence-gathering operation."

However, it is clear that long-term positive relationships between U.S. military and partner country public health authorities in some regions have overcome such concerns. In some countries, U.S. military laboratories have been in existence for decades, are well respected, and are seen as important in supporting local diagnostic and surveillance capabilities.

"There are some countries where being part of DoD actually is going to help you—Georgia and Azerbaijan are great examples. Both of those countries are extremely concerned that Russia is going to invade them. And so having any type of relationship with the DoD is important to them . . . and it provides an opportunity to engage them on health."

"It's a matter of picking and choosing and figuring out which countries for their own strategic purposes want to establish a relationship with the U.S. DoD. For countries where a relationship with DoD is not a viable option, CDC, HHS, USDA, USAID, and other agencies may be better able to build those relationships."

Participants suggested that U.S. military disease surveillance programs are more likely to be seen as assets to a host country when the programs are structured to address local public health priorities and when they are transparent about the data they will use and how they will use them. NAMRU-3 in Cairo, Egypt, which focuses considerable effort on local health issues, is an example of a successful engagement with the local public health community. To that end, the U.S. may want to develop explicit agreements with host countries about the types of data to be collected, who will have access, and how it will be used.

"A first priority should be to build a system that can be used locally to intervene in routine public health threats. The more people work together, the more apt they will be to share information."

"The development of data stewardship protocols is important to encourage countries to share data with the international community."



Center for Biosecurity Recommendations

The following recommendations for improving international disease surveillance represent the Center's independent assessment, based on our literature review and analysis, interviews with experts, and advisory input from the Center's expert workshop on international disease surveillance.

1. IMPROVE STRATEGY AND COORDINATION

The USG should develop a comprehensive strategy to guide future programs and investments in international disease surveillance; doing so will enhance opportunities for the U.S. to meet its major goals for international disease surveillance. Involvement of multiple USG agencies in international disease surveillance and the existence of multiple goals will require enhanced coordination across the USG. This may help to ensure that distinct goals are being pursued effectively and that agencies are not working unintentionally at cross-purposes and/or duplicating efforts. The USG should continue working to develop a better interagency process for coordinating the international disease surveillance programs that exist across the federal government. These efforts should include strategies for coordinating with foreign governments and NGOs that may also be involved in international disease surveillance efforts.

2. ADDRESS IN-COUNTRY SURVEILLANCE PRIORITIES

USG international disease surveillance programs should include support for local surveillance and response priorities. Improving local capacity to address routine infectious disease needs of host countries will improve or lead to the technical ability to detect and respond to emerging infectious diseases and other health security threats. It will also serve to increase local support for USG and other nongovernmental disease surveillance programs.

3. TIE SURVEILLANCE PROGRAMS TO PUBLIC HEALTH ACTIONS

To the greatest extent possible, the development of disease surveillance programs should be tied to public health action. Surveillance data collected should be continually evaluated for its role in informing public health decisions and interventions. After-action reports from exercises and real public health emergencies should be used to evaluate the ability of surveillance systems to provide actionable information to guide public health response to health threats.

4. EXPAND GLOBAL LAB CAPACITY FOR HUMAN AND ANIMAL DISEASES

USG disease surveillance programs should continue to support efforts to expand global laboratory and diagnostic capacity for both human and animal diseases in order to improve detection and management of infectious disease threats. In addition to supporting development of specific plans for appropriately increasing laboratory capacity worldwide, the USG would be wise to invest in efforts to develop rapid, point-of-care diagnostic tests that can quickly identify people who are ill and help in isolating contagious people.

5. MAINTAIN TRANSPARENCY AND STEWARDSHIP OF SURVEILLANCE DATA

In engaging foreign governments for the purposes of international disease surveillance, USG agencies should work to alleviate concerns that foreign public health surveillance data will be used for U.S. intelligence, military, or commercial applications. Most important to this effort are continual maintenance of transparency, good stewardship of host country disease surveillance data, and continued support of surveillance programs that produce tangible benefits to host nations by addressing local disease priorities and providing data that can be used to inform public health action.

6. DEVELOP A CADRE OF SKILLED IN-COUNTRY PERSONNEL TO STAFF AND MANAGE DISEASE SURVEILLANCE SYSTEMS

The success of any disease surveillance program will depend upon skilled personnel who have local knowledge and are well-trained in epidemiology and laboratory methods (including biosafety and quality control). However, in much of the world there are critical shortages of such workers. To address this issue, the USG should continue to support efforts to train in-country personnel to staff and manage surveillance programs. To that end, the USG should consider expanding existing training programs, such as the CDC's Field Epidemiology Training Program (FETP) and Field Epidemiology Laboratory Training Program (FELTP). These 2 training efforts are generally well-regarded, and new efforts by FELTP to train veterinary health professionals to participate in surveillance for zoonoses is a promising development.

7. USER REQUIREMENTS SHOULD DRIVE DEVELOPMENT OF FLEXIBLE SURVEILLANCE TOOLS THAT, AT A MINIMUM, SUPPORT CONNECTIONS BETWEEN PUBLIC HEALTH AND HEALTHCARE SECTORS.

Lessons from previous outbreaks have demonstrated that, in many areas, connections between public health and healthcare sectors are not sufficient to support effective detection of and response to outbreaks. The USG should support development of flexible tools to support improved communication between these 2 sectors. However, rather than approaching partner countries with a particular tool or technology in hand, the USG should first assess the specific needs of users in host countries. Such an assessment should be completed prior to systemic deployment of a surveillance technology or tool and should involve all stakeholders, including data providers, data users, and the host country's ministry of health.

APPENDIX A. Project Participants

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